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Topics addressed

- ♦ I. Protecting the interests of oocyte donors
- ♦ II. Making informed decisions when data are inconclusive
- ♦ III. Making informed decisions when interventions may result in inheritable modifications



I. Protecting the interests of oocyte donors



Sample guidelines for ART and oocyte donation

- *Elements To Be Considered in Obtaining Informed Consent for ART* (ASRM Practice Committee 1997)
- *Guidelines for Oocyte Donation* (ASRM Practice Committee 2002)
- *Informed Consent and the Use of Gametes and Embryos for Research* (ASRM Ethics Committee 1997)
- *Financial Incentives in Recruitment of Oocyte Donors* (ASRM Ethics Committee 2000)
- *Repetitive Oocyte Donation* (ASRM 2001)



Some topics covered in 2002 oocyte donation guidelines

- *Indications for use*
- *Evaluation of recipient and recipient's partner*
- *Selection of donors (anonymous v. known, age, proven fertility, sharing of oocytes)*
- *Psychological evaluation*
- *Screening and testing of donors (risk factors identified)*
- *Payment*
- *Multiple donations*
- *Record-keeping, consent, legal consultation*



Purposes of donation

- Oocytes for procreation
- Oocytes for research
- Ooplasm to assist procreation
 - Ooplasm transfer (OT)
 - 5-15% ooplasm injected to recipient egg
 - First birth 1997; ~ 30 births by 2002
 - On hold



Risk/benefit to donors

- ◆ Oocytes for procreation
 - Potential benefit (altruism): high
 - Potential emotional risk: high
 - Health risks
- ◆ Ooplasm to assist procreation
 - Potential benefit (altruism): medium
 - Potential emotional risk: low
 - Health risks



Donating for ooplasm transfer

- ◆ Compensation
 - “Payment should not be predicated on clinical outcome”
 - “Monetary compensation . . . should reflect the time, inconvenience, and physical and emotional demands and risks”
 - “Payments . . . should be fair and not so substantial that they become undue inducements that will lead donors to discount risks.”



◆ Potential limits on donation

- Fewer constraints than whole oocyte donation (e.g., inadvertent consanguineous mating)
- Health risks
- Age
- Previous motherhood
- Psychological counseling



◆ Other issues

- Family pressures to donate
- Privacy protection
- Notification of adverse outcomes from testing
- Clarifying that will not be genetic parent
- Legal consultation



II. Making informed decisions when data about safety and efficacy are inconclusive



- ◆ 1. The health of children is at issue
- ◆ 2. Patients thought to be vulnerable
- ◆ 3. Patients often pay out of pocket
- ◆ 4. Animal data and ICSI
- ◆ 5. Research involving human embryos not publicly funded



Some questions to ask

- ♦ Will this pose risks to my child?
- ♦ Will this pose risks to me?
- ♦ Have benefits been documented?
- ♦ Have harmful effects been documented?
- ♦ Will this benefit someone with my condition?



Some questions to ask

- ♦ What is this clinic's experience with the procedure?
- ♦ What are alternatives to the procedure, including adoption and deciding not to treat?



Making decisions when data are inconclusive

- ◆ Access to clear and manageable information
- ◆ Access to neutral information
- ◆ Interpreting animal-based studies
- ◆ Understanding status of procedure
- ◆ Styles of decision-making involving risk
- ◆ Interactive consent process
- ◆ Deciding who pays



III. Making informed decisions when interventions may result in inheritable modifications



Two categories of inheritable modifications

- ♦ Alterations to nuclear DNA
 - Performed with animals
 - Not on immediate horizon for humans
- ♦ Alterations to cytoplasm (mtDNA)
 - Ooplasm transfer and heteroplasmy reported in at least 2 children
 - On hold



Differing perspectives on OT

- ♦ *Permissive*: should proceed with existing oversight mechanisms
- ♦ *Cautionary*: proceeding may eventually be possible with heightened oversight
- ♦ *Prohibitive*: should never proceed



♦ *Permissive:*

- Inheritance of mtDNA not automatically troublesome
- Foreseeable benefits (broad)
- Is primarily a matter of parental autonomy
- Implication: consent may be given when safety and efficacy demonstrated



♦ *Cautionary:*

- Inheritance of mtDNA troublesome
- Benefits are visualized (narrow)
- Societal and individual interests are balanced
- Implication: consent eventually may be given if conditions are met (data collection, new oversight body and/or IND process, public discussion)



♦ *Prohibitive:*

- mtDNA crosses a line and sets the stage for nDNA alterations
- Is no clear benefit; less problematic alternatives available
- Societal interests outweigh individual choice
- Implication: consent to proceed may not be given by couples even if safety is assured



♦ Making informed decisions if OT proceeds under cautionary approach

- Core informed consent guidelines
- Guidelines when data inconclusive
- Animal data across generations
- Access to clear information about data reported in IND application
- Emotions if child's health compromised



Building on informed consent

- ◆ Start with core informed consent guidelines
- ◆ Premium on decipherable information
- ◆ Study how patients perceive and act on risk
- ◆ Public/private data gathering and distribution (FCSRA model)